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| APPLICATION NO.                             | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO |
|---|-----------------|----------------------|--------------------------|-----------------|
| 09/911,692                                  | 07/25/2001      | Darrell R. Anderson  | 27693-01009              | 8484            |
| 47553                                       | 7590 09/13/2006 |                      | EXAMINER                 |                 |
| SIDLEY AUSTIN LLP ATTN: DC PATENT DOCKETING |                 |                      | SCHWADRON, RONALD B      |                 |
| 1501 K STREET, NW<br>WASHINGTON, DC 20005   |                 |                      | ART UNIT                 | PAPER NUMBER    |
|   |                 |                      | 1644                     |                 |
|   |                 |                      | DATE MAIL ED: 00/13/2004 | 4               |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.      | Applicant(s)    |  |  |  |  |
|--|----------------------|-----------------|--|--|--|--|
| Office Action Summany  | 09/911,692           | ANDERSON ET AL. |  |  |  |  |
| Office Action Summary  | Examiner             | Art Unit        |  |  |  |  |
|  | Ron Schwadron, Ph.D. | 1644            |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |                      |                 |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                      |                 |  |  |  |  |
| Status   |                      |                 |  |  |  |  |
| 1) Responsive to communication(s) filed on   |                      |                 |  |  |  |  |
|  | action is non-final. |                 |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |                      |                 |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                      |                 |  |  |  |  |
| Disposition of Claims  |                      |                 |  |  |  |  |
| 4)⊠ Claim(s) <u>70-78</u> is/are pending in the application.   |                      |                 |  |  |  |  |
| 4a) Of the above claim(s) <u>76-78</u> is/are withdrawn from consideration.  |                      |                 |  |  |  |  |
| 5) Claim(s) is/are allowed.  |                      |                 |  |  |  |  |
| 6)⊠ Claim(s) <u>70-75</u> is/are rejected.   |                      |                 |  |  |  |  |
| 7) Claim(s) is/are objected to.  |                      |                 |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |                      |                 |  |  |  |  |
| Application Papers   |                      |                 |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |                      |                 |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |                      |                 |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |                      |                 |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  |                      |                 |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |                      |                 |  |  |  |  |
|  |                      |                 |  |  |  |  |
| Priority under 35 U.S.C. § 119   |                      |                 |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |                      |                 |  |  |  |  |
| <ol> <li>Certified copies of the priority documents have been received.</li> </ol>   |                      |                 |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |                      |                 |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |                      |                 |  |  |  |  |
| application from the International Bureau  |                      | Č               |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |                      |                 |  |  |  |  |
|  |                      |                 |  |  |  |  |
|  |                      |                 |  |  |  |  |
| Attachment(s)  |                      |                 |  |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 4) Interview Summary | (PTO-413)       |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)   |                      |                 |  |  |  |  |
| Paper No(s)/Mail Date 6)  Other:   |                      |                 |  |  |  |  |

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1. Applicant's election without traverse of Group I in the reply filed on 6/23/06 is acknowledged.

- 2. Claims 76-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 11/14/2003. Applicants request for rejoinder is noted.
- 3. Claims 70-75 are under consideration.
- 4. The abstract of the disclosure is objected to because it does not disclosed the claimed host cells.
- 5. The drawing correction received 8/22/05 is approved.
- 6. Applicant is required to correct the inventorship of the instant application in view of the currently claimed invention and in light of statements regarding inventorship made in the petition to correct inventorship filed in parent 08/149099 and petitions to correct inventorship filed in other child cases of 08/149099.
- 7. Applicant is required to update the status of all US applications disclosed in the instant application (including those other than on page 1 of the specification).
- 8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

  The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 9. Claims 70-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the host cell of claim 70/72. The claims encompass host cells that express nucleic acids encoding membrane bound anti-CD20 antibody, yet there is no disclosure of such cells in the specification as originally filed. The claims encompass host cells that express the nucleic acid recited in the claims in the absence of additional regulatory nucleic acid sequences required for secretion of the antibody yet such cells are not disclosed in the specification. The claims encompass host cells that only contain the specific nucleic acid recited in the claims wherein such host cells are not disclosed in the specification as originally filed. Regarding applicants comments about the specification, page 24, said page discloses that the host cell is transfected with a plasmid, wherein the claimed host cell does not require presence of plasmid associated nucleic acids as per disclosed in the specification. In addition, based on the teachings of the specification (such as page 42), it appears that the plasmid would require specific sequences required for expression and secretion of the chimeric antiCD20 antibody. There is no support in the specification as originally filed for the scope of the claimed invention (aka the claimed inventions constitute new matter).

## 10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 517 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.

**Primary Examiner** 

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RONALD B. SCHWADRON PRIMARY EXAMINER

GROUP-1800 (647

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